

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

PFIZER INC.,)
PFIZER IRELAND PHARMACEUTICALS,)
WARNER-LAMBERT COMPANY, and)
WARNER-LAMBERT COMPANY LLC,)
)
Plaintiffs,)
)
v.) Civil Action No. _____
)
KREMERS URBAN, LLC, and)
KUDCO IRELAND, LTD.,)
)
Defendants.)
)

COMPLAINT

Pfizer Inc., Pfizer Ireland Pharmaceuticals, and Warner-Lambert Company LLC, formerly Warner-Lambert Company (collectively, "Pfizer"), by their attorneys, for their Complaint against Kremers Urban, LLC ("Kremers Urban") and KUDCO Ireland, Ltd. ("KUDCO Ireland") (collectively, "Defendants"), allege as follows:

1. This is an action by Pfizer against Defendants for infringement of U.S. Patent No. 5,969,156 and its Reexamination Certificate (collectively, "the '156 patent"). A copy of the '156 patent with the '156 Reexamination Certificate is attached hereto as Exhibit A.

PATENT IN SUIT

2. On October 19, 1999, the United States Patent and Trademark Office (USPTO) issued the '156 patent, entitled "Crystalline [R-(R*,R*)]-2-(4-Fluorophenyl)- β,δ -Dihydroxy-5-(1-Methylethyl)-3-Phenyl-4-[(Phenylamino)Carbonyl]-1H-Pyrrole-1-Heptanoic Acid Hemicalcium Salt (Atorvastatin)", on an application filed by Christopher Briggs, *et al.*, and

assigned to Warner-Lambert Company. On September 26, 2006, the USPTO issued an Ex Parte Reexamination Certificate for the '156 patent.

PARTIES, JURISDICTION AND VENUE

3. Pfizer Inc. is a corporation organized and existing under the laws of the State of Delaware and has a place of business at 235 East 42nd Street, New York, New York 10017.
4. Warner-Lambert Company is a corporation formerly organized under the laws of the State of Delaware with offices for service of process at 235 East 42nd Street, New York, New York 10017. Warner-Lambert Company has been the owner of record of the '156 patent since its issuance.
5. Warner-Lambert Company became a wholly owned subsidiary of Pfizer Inc. effective June 19, 2000.
6. Warner-Lambert Company was converted into a Delaware limited liability company and changed its name to Warner-Lambert Company LLC on December 31, 2002. Warner-Lambert Company LLC has offices located at 235 East 42nd Street, New York, New York 10017.
7. Pfizer Ireland Pharmaceuticals is a partnership, organized and existing under the laws of Ireland, with registered offices at Pottery Road, Dun Laoghaire, County Dublin, Ireland. Pfizer Ireland Pharmaceuticals is a wholly owned, indirect subsidiary of Pfizer Inc.
8. Pfizer Ireland Pharmaceuticals is the exclusive licensee of the '156 patent.
9. Pfizer has all the right, title, and interest in the '156 patent and the right to sue for infringement thereof.

10. Pfizer holds an approved New Drug Application for atorvastatin calcium formulations, including 10 mg, 20 mg, 40 mg and 80 mg dosage strengths, which it sells under the registered name Lipitor®.

11. The '156 patent is identified pursuant to 21 U.S.C. §355(b)(1) and (j)(7) by the United States Food and Drug Administration ("FDA") as covering Pfizer's Lipitor® products.

12. By letter dated October 22, 2009 (the "ANDA Notice Letter"), Defendants notified Pfizer that Defendants had filed Abbreviated New Drug Application ("ANDA") No. 91-624 seeking FDA approval to market atorvastatin calcium tablets in 10 mg, 20 mg, 40 mg and 80 mg dosage strengths, and that Defendants were providing information to Pfizer pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95(a). A copy of the ANDA Notice Letter on Kremers Urban's letterhead is attached hereto as Exhibit B.

13. On information and belief and as stated in the ANDA Notice Letter, Defendant Kremers Urban has a principal place of business at 301 Carnegie Center, Suite 300, Princeton, NJ 08540.

14. On information and belief, Defendant Kremers Urban is resident in the State of Delaware, it being a limited liability company operating and existing under the laws of Delaware.

15. Kremers Urban's Delaware registered agent is the Corporation Trust Company, 1209 Orange Street, Wilmington, DE 19801.

16. On information and belief, Defendant KUDCO Ireland is a single member private company existing under the laws of Ireland and having a principal place of business at Shannon Industrial Estate, Shannon, County Clare, Ireland.

17. On information and belief, KUDCO Ireland is a sister corporation of Kremers Urban.

18. On information and belief, KUDCO Ireland does not reside or have a place of business in the United States.

19. On information and belief and as stated in the ANDA Notice Letter, the FDA received ANDA No. 91-624 from KUDCO Ireland.

20. On information and belief and as stated in the ANDA Notice Letter, Kremers Urban is the United States agent for KUDCO Ireland and is responsible for ANDA No. 91-624. Kremers Urban, according to said Letter, communicated with FDA as KUDCO Ireland's U.S. agent at least with respect to the manner of service of that Letter on Pfizer.

21. On information and belief, Kremers Urban, as the agent of KUDCO Ireland and/or in its own capacity, participated in the preparation and/or filing of ANDA No. 91-624 and in subsequent communications with and from FDA in connection with said ANDA.

22. On information and belief, Kremers Urban countersigned ANDA No. 91-624 pursuant to 21 C.F.R. § 314.50(a)(5) and 314.94(a)(1).

23. On information and belief, Kremers Urban stands to benefit from any FDA approval of ANDA No. 91-624.

24. On information and belief and as stated in the ANDA Notice Letter, KUDCO Ireland designated Kremers Urban as its United States agent responsible for the ANDA and to accept service of process pursuant to 21 C.F.R. § 314.95(c)(7).

25. This action arises under the Patent Laws of the United States, Title 35, United States Code. This Court has subject matter jurisdiction over this action pursuant to the provisions of Title 28, United States Code, Sections 1331 and 1338.

26. Personal jurisdiction over Kremers Urban is proper because Kremers Urban expressly consented to general personal jurisdiction in the State of Delaware by appointing a resident of Delaware as its agent for service of process.

27. Personal jurisdiction over Kremers Urban is also proper because, on information and belief, Kremers Urban maintains continuous and systematic contacts with the State of Delaware, including the sale and use of Kremers Urban's products in Delaware, so as to reasonably allow jurisdiction to be exercised over it.

28. Personal jurisdiction over Kremers Urban is also proper because, on information and belief, Kremers Urban is registered as a limited liability company in the State of Delaware and has purposely availed itself of the privilege of doing business in this State.

29. Personal jurisdiction over Kremers Urban is also proper because it has affirmatively sought relief in the Delaware courts and has employed Delaware counsel to assist in obtaining the relief sought.

30. On information and belief, personal jurisdiction over KUDCO Ireland is proper because KUDCO Ireland expressly consented to general personal jurisdiction in the State of Delaware by appointing a Delaware resident as its agent for service of process.

31. On information and belief, personal jurisdiction over KUDCO Ireland is also proper because, to the extent that Kremers Urban acted at the direction of, for the benefit of, or on behalf of KUDCO Ireland, such actions within or directed to the State of Delaware are attributable to KUDCO Ireland.

32. On information and belief, personal jurisdiction over KUDCO Ireland is also proper because it has affirmatively sought relief by filing counterclaims in the Delaware courts and has employed Delaware counsel to assist in obtaining that relief.

33. On information and belief, personal jurisdiction over KUDCO Ireland is also proper because KUDCO Ireland is a co-filer of ANDA No. 91-624 and will be served within 100 miles of where the summons is issued.

34. KUDCO Ireland will be served within 100 miles of where the summons is issued because, on information and belief, both 1209 Orange Street, Wilmington, DE 19801 and 301 Carnegie Center, Suite 300, Princeton, NJ 08540 are within 100 miles of the Delaware District Courthouse, 844 North King Street, Wilmington, DE 19801.

35. On information and belief, personal jurisdiction over Defendants is proper because by filing their ANDA No. 91-226 for generic atorvastatin calcium tablets, they have committed the tort of patent infringement pursuant to 35 U.S.C. § 271(e)(2)(A) and the location of that tort is where the patent holder, Pfizer, resides, *i.e.*, in Delaware.

36. Venue is proper in this District pursuant to the provisions of Title 28, United States Code, Sections 1391(c) and (d), and 1400(b).

**FIRST CLAIM FOR RELIEF:
INFRINGEMENT OF THE ‘156 PATENT**

37. The allegations of paragraphs 1-36 above are repeated and realleged as if set forth fully herein.

38. The expiration date for the ‘156 patent is July 8, 2016.

39. Patents associated with Lipitor®, including the ‘156 patent, have been granted a further period of pediatric exclusivity under section 505a of the Food, Drug and Cosmetic Act [21 U.S.C. § 355a].

40. The pediatric exclusivity period associated with the ‘156 patent will expire January 8, 2017.

41. The ANDA Notice Letter notified Pfizer that Defendants, by filing ANDA No. 91-624, seek approval from the FDA to engage in the commercial manufacture, use, and sale of products containing different strengths of atorvastatin calcium prior to the expiration of the '156 patent.

42. The ANDA Notice Letter contained an offer to provide certain confidential information from ANDA No. 91-624 purportedly pursuant to 21 U.S.C. § 355(j)(5)(C) and attached a Request for Confidential Access for Information directed to both Kremers Urban and KUDCO Ireland, "collectively Kremers."

43. The purported offer of confidential access, including the attached request, imposed restrictions on the access and use of the information not contemplated or permitted by 21 U.S.C. § 355(j)(5)(C)(III).

44. The ANDA Notice Letter addressed the '156 patent, and both KUDCO Ireland and Kremers Urban asserted that the '156 patent was invalid and/or not infringed by Defendants' proposed ANDA No. 91-624 atorvastatin calcium products.

45. Defendants have infringed the '156 patent under 35 U.S.C. § 271(e)(2)(A) by filing ANDA No. 91-624 seeking approval from the FDA to engage in the commercial manufacture, use, or sale of products containing various strengths of atorvastatin calcium prior to the expiration of the '156 patent.

46. Pfizer will be irreparably harmed if Defendants' ANDA No. 91-624 is approved prior to the expiration date of the '156 patent.

47. Pfizer will be irreparably harmed if Defendants are not enjoined from infringing the '156 patent.

PRAYER FOR RELIEF

WHEREFORE, Pfizer requests the following relief:

- A. A judgment providing that pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any FDA approval for Defendants' ANDA No. 91-624 be no earlier than January 8, 2017, the date of expiration of the '156 Patent including the period of exclusivity granted to Lipitor® under section 505a of the Food, Drug and Cosmetic Act;
- B. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) permanently enjoining Defendants, each of their officers, agents, servants, employees and attorneys, and those persons in active concert or participation with it or any of them, from making, using, selling, offering to sell, or importing the atorvastatin calcium products described in Defendants' ANDA No. 91-624 until January 8, 2017, the expiration date of the '156 patent, including the period of exclusivity granted to Lipitor® under section 505a of the Food, Drug and Cosmetic Act;
- C. Attorneys' fees in this action pursuant to 35 U.S.C. § 285;
- D. Costs and expenses in this action; and
- E. Such further and other relief as this Court may deem just and proper.

RESPECTFULLY SUBMITTED,

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Dated: December 3, 2009
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